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# ANNUAL PROGRESS REPORT FY-92

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**CLINICAL INVESTIGATION SERVICE  
WOMACK ARMY MEDICAL CENTER  
FORT BRAGG, NC 28307-5000**

**CLINICAL INVESTIGATION PROGRAM**

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4. TITLE AND SUBTITLE Clinical Investigation Program RCS MED-300(R1)		5. FUNDING NUMBERS		
6. AUTHOR(S) VICTOR G. McGLAUGHLIN, M.D. MAJOR, MEDICAL CORPS Director, Clinical Investigation				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Clinical Investigation Service Womack Army Medical Center Fort Bragg, North Carolina 28307-5000		8. PERFORMING ORGANIZATION REPORT NUMBER  RCS MED-300(R1)		
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12a. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release: Distribution unlimited		12b. DISTRIBUTION CODE		
13. ABSTRACT (Maximum 200 words) This report identifies approved clinical research activities conducted at Womack Army Medical Center through protocols approved by the Clinical Investigation Committee and Human Use Committee/Institutional Review Board. This report includes a Detail Summary Sheet outlining the progress of each protocol during Fiscal Year 92. Also included is a list of all known presentations and publications by Womack Army Medical Center professional staff. All research was conducted under the provisions of AR 40-38 (Clinical Investigation Program), AR 40-7 (Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances), AR 70-25 (Use of Volunteers as Subjects of Research) and HSC Reg 40-23 (Management of Clinical Investigations, Protocols and Reports).				
14. SUBJECT TERMS APR - Annual Progress Report, PI - principal investigator, protocol, study objective, technical approach, prior and current progress, conclusions, status, publications			15. NUMBER OF PAGES	
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# FOREWARD

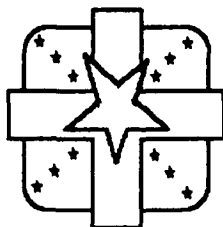
Clinical Investigation was approved as a modified mission for Womack Army Community Hospital in May, 1990. Due to the deployments in support of Operation Desert Shield/Desert Storm, our first efforts at the research review and approval process did not take place until the Fall of 1991. Significantly, Womack was designated a medical center that same autumn. This Annual Progress Report is therefore an historic document, recording our steps as we grow into the role of a medical center.

More fertile ground than Fort Bragg for patient-oriented, clinically-based scholarly activity could not be imagined. With approximately 50,000 active duty members and over 200,000 beneficiaries in our catchment, the clinical material is indeed ample. Certainly, this population is recognized by the Walter Reed Army Institute of Research, and the U.S. Army Medical Research Institute for Infectious Disease, who (among others) periodically conduct studies at Fort Bragg. Sadly, the involvement of the Womack clinicians in research is low simply because the patient care burden is high. My hope is that the potential of Fort Bragg for patient-based research of military medical significance will be fully recognized in the years ahead. I also hope that, as scarce personnel resources are re-aligned in the Army medical community, these individuals will be appropriately committed toward the realization of this immense potential.

I remain indebted to the leadership of Womack Army Medical Center for their commitment to an entry-level clinical investigation program. It would not have occurred without the support of the Commander, Colonel Mike Casey, and the DCCS, Colonel Kevin Kiley. LTC Joe FitzHarris, as Chief of the Department of Family Practice, enabled a physician and secretary to be committed to the Clinical Investigation Service. Certainly, our efforts pale when compared with those of larger, established programs. As the proverb goes, however, A journey of a thousand miles begins with a single step. I am personally grateful for the opportunity to take the step.

*V. G. McGlaughlin, Jr.*

Victor G. McGlaughlin, Jr., M.D.  
Major, Medical Corps  
Director, Clinical Investigation Service



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# I. UNIT SUMMARY

## A. OBJECTIVE

To implement and manage the Clinical Investigation program at Womack Army Medical Center (WAMC), Fort Bragg, North Carolina by promoting, supporting, coordinating, and providing the atmosphere of inquiry necessary to stimulate clinical medical investigation.

## B. TECHNICAL APPROACH

The Clinical Investigation program at WAMC is conducted by careful monitoring of all approved protocols to assure strict compliance with the following applicable regulations:

AR 40-7	Use of Investigation Drugs in Humans and the Use of Schedule I Controlled Drug Substances
AR 40-38	Clinical Investigation Program
AR 70-25	Research and Development Use of Volunteers as Subjects of Research
AR 40-37	Licensing and Control of Radioactive Materials for Medical Purposes
HSC 40-23	Management of Clinical Investigation Protocols and Reports

## C. STAFFING

DESCRIPTION	RANK	MOS	BRANCH	NAME
Director	O4	61H	MC	McGlaughlin, VG
Protocol Coordinator	O4	0679	GS	Collazo, KL
FACT Coordinator				Wolf, T

**TABLE I. WAMC Protocol Activity**

PROTOCOLS	FY-91	FY-92
ONGOING at the beginning of FY	0	0
Newly Approved (+)	0	13
TOTAL ACTIVE during FY	0	13
COMPLETED (-)	0	3
TERMINATED (-)	0	1
ONGOING at the end of FY	0	9

**TABLE II. WAMC FY-92 Active Investigations by AMEDD Officer Corps**

CORPS	NUMBER	ACTIVE STUDIES
Medical Corps	11	8
Medical Service Corps	0	0
Medical Specialist Corps	1	1
Dental Corps	1	0
Army Nurse Corps	0	0
Veterinary Corps	0	0
	13	9

**TABLE III. WAMC FY-92 Active Investigations by Subject**

Subject	Terminated	Completed	Active Studies
Human:			
Investigational New Drug	1	0	4
Investigational Device	0	0	1
Descriptive - Expedited	0	3	3
- Greater Risk	0	0	1
Animal	0	0	0
Laboratory	0	0	0
Total	1	3	9

**TABLE IV. WAMC Clinical Investigation Publications and Presentations**

	FY-92
Published Articles	13
Abstracts	1
Presentations	36
Total	50

# RESEARCH AWARDS

Recipient of

First Place Award in the  
**RESIDENT CLINICAL INVESTIGATION**  
category was

**CAPTAIN MICHAEL SCHOOFF, MC, FAMILY PRACTICE RESIDENT**  
for his paper

**"Influences in Medical Specialty Selection of the 1991  
Graduates of the Uniformed Services University of the  
Health Sciences"**

This paper was presented at the XVIIth Annual Uniformed Services Academy of Family Physicians Scientific Assembly in Oakland, California, May 1992.

Recipient of

**BEST SCIENTIFIC PAPER AWARD**  
was

**CAPTAIN DAVID LUX, MC, FAMILY PRACTICE PHYSICIAN**  
for his paper

**"Falciparum Malaria in Pregnancy"**

This paper was presented at the Southern Medical Association Annual Scientific Assembly in Atlanta, Georgia, November 1991.

Recipient of

**FOUNDERS AWARD FOR BEST MILITARY RESEARCH**  
was

**MAJOR JAMES P. STANNARD, MC, DEPARTMENT OF SURGERY**  
for his paper

**"Pressure Absorption During Parachute Landing Falls"**

This paper was presented at the Society of Military Orthopaedic Surgeons in El Paso, Texas, Nov. 1991.

## Clinical Investigation Committee Members

Kevin C. Kiley, COL MC	Chairman Deputy Commander for Clinical Services
Victor G. McGlaughlin, MAJ MC	Co-Chairman Director, Clinical Investigation Service
Edward Freyfogle, COL MC	Chief Department of Surgery
Anthony Courtney, COL MC	Chief Department of Medicine
Manuel Fuentes-Canales, LTC MC	Chief Department of OB/GYN
Bonnie MacGhee, LTC AN	Representing Chief Department of Nursing
Sharon Cooper, LTC MC	Chief Department of Pediatrics
George Suchko, LTC MC	Chief WAMC Dental Activities
Kelly McKee, LTC MC	Chief Preventive Medicine Service
Robert Sikora, LTC MS	Chief Pharmacy Service
Joseph FitzHarris, LTC MC	Chief Department of Family Practice
Elizabeth Mooney, LTC MC	Chief Department of Radiology
Ronald Dutton, LTC VC	Deputy Commander for Veterinary Services
Thomas Jewell, MAJ MS	Chief Department of Pathology
Thomas Dudley, MAJ CH	Chaplain Chief, Ministry and Pastoral Care
Earl Parson, MAJ MC	Representing Chief Department of Psychiatry/Neurology
Darren Fong, ILT MS	Representing Chief Social Work Service
Henry Gibson, CSM	Lay/Non-affiliated Representative 307th Medical Battalion



# **Human Use Committee / Institutional Review Board Members**

**Kevin Kiley, COL MC**

**Chairman  
Deputy Commander for Clinical Services**

**Victor McGlauglin, MAJ MC**

**Co-Chairman  
Director, Clinical Investigation**

**Bonnie MacGhee, LTC AN**

**Representing Chief  
Department of Nursing**

**Thomas Dudley, MAJ CH**

**Chaplain  
Chief, Ministry and Pastoral Care**

**Earl Parson, MAJ MC**

**Representing Chief  
Department of Psychiatry/Neurology**

**Linda Taylor, CPT JA**

**Chief, Claims Office  
Center Judge Advocate**

**Henry Gibson, CSM**

**Lay/Non-affiliated Representative  
307th Medical Batallion**

## II. PROTOCOL NUMBER, PRINCIPAL INVESTIGATOR, TITLE, AND APPROVAL DATE

BY DEPARTMENT AND SERVICE

<u>PROTOCOL NUMBER</u>	<u>PRINCIPAL INVESTIGATOR, TITLE, AND APPROVAL DATE</u>	<u>PAGE</u>
<b><i>DENTAL ACTIVITY</i></b>		
92007	Davis, Randy MAJ, DC. Fluoride concentrations in Human Bone. (3/92)	21
<b><i>DEPARTMENT OF FAMILY MEDICINE</i></b>		
92001	McGlaughlin, Victor MAJ, MC. The Nedocromil Sodium Inhalation Aerosol Clinical Experience Study: An Evaluation of Nedocromil Sodium Inhalation Aerosol in Symptomatic Patients with Mild to Moderate Asthma. (10/91)	15
92003	Weightman, George LTC, MC. A Comparison of the Efficacy, Safety, and Tolerance of Ceftributen 300mg Given BID and Augmentin 500mg Given TID in the Treatment of Community Acquired Pneumonia. (1/92)	17
92004	Greenberg, Bruce CPT, MC. A Comparison of the Efficacy, Safety, and Tolerance of Ceftributen 400mg in the fed and fasted state and Augmentin Amoxicillin/Clavulante 1.5gm in the fed state in Treatment of Acute Exacerbations of Chronic Bronchitis. (1/92)	18
92005	McGlaughlin, Victor MAJ, MC. The Influence of Work on the Outcome of Pregnancy in Military and Non-Military Nulliparous Women. (1/92)	19
92006	McGlaughlin, Victor MAJ, MC. Tick-Borne Disease Surveillance in Febrile, Hospitalized Patients. (2/92)	20
92008	Goforth, Gary LTC, MC. Fort Bragg Tick-Borne Disease Study: Womack Family Practice Clinic (non-active duty outpatients). (2/92)	22

## II. PROTOCOL NUMBER, PRINCIPAL INVESTIGATOR, TITLE, AND APPROVAL DATE (cont)

BY DEPARTMENT AND SERVICE

<b><u>PROTOCOL NUMBER</u></b>	<b><u>PRINCIPAL INVESTIGATOR, TITLE, AND APPROVAL DATE</u></b>	<b><u>PAGE</u></b>
<b><i>DEPARTMENT OF MEDICINE</i></b>		
92002	Swackhammer, Randy MAJ, MC. Long-acting Converting Enzyme Inhibition Use in Elderly, Hypertensive Patients: A Nationwide Survey. (12/91)	16
92011	Williams, Richard MAJ, MC. A double-blind, placebo controlled, parallel group, multicenter study of the use of weekly Azithromycin as prophylaxis against the development of Mycobacterium Avium Complex Disease in HIV infected people. (5/92)	25
<b><i>PREVENTIVE MEDICINE SERVICE</i></b>		
92012	Craig, Stephen MAJ, MC. [WRAIR] The Prevalence of Degenerative Joint Disease of the Spine in Airborne Infantry, Non-Airborne Infantry, and Non-Airborne Combat Service Support Personnel. (2/92)	26
92013	Sjogren, Maria LTC, MC. [USAMRIID] Immunization of Military Personnel with Hepatitis A Vaccine. (9/92)	27
<b><i>DEPARTMENT OF RADIOLOGY</i></b>		
92010	Burke, Brian CPT, MC. Ultrasound Guided Percutaneous Needle Core Breast Biopsy. (3/92)	24
<b><i>DEPARTMENT OF SURGERY</i></b>		
92009	O'Keefe, Ellen 1LT, MS. A Comparison of Functional Recovery Rates using Circumferential, Collateral and Focal Continuous Compression following Grade II Ankle Inversion Injuries. (3/92)	23

### III. PUBLICATIONS, PRESENTATIONS, AND ABSTRACTS

BY DEPARTMENT/SERVICE AND AUTHOR

\*TYPE

#### DENTAL ACTIVITY

- |                                                                                                                                                                                  |    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| Suchko G: TMJ Disorders: Assessment and Treatment. Greater Fayetteville Dental Society, Fayetteville, North Carolina, November, 1991.                                            | Pr |
| Suchko G: Oral and Maxillofacial Trauma (Part 1) Wartime Readiness. Pope Air Force Base Dental Officers, Pope Air Force Base, October, 1992.                                     | Pr |
| Shields W: Regenerative Periodontal Therapy - Part I and II Fayetteville Dental Hygiene Society, April 1992.                                                                     | Pr |
| Shields W: Mucogingival Therapy, Adjunctive Therapy and Regenerative Therapy, Fort Riley, Kansas, May, 1992.                                                                     | Pr |
| Shields W: Adjunctive Periodontal Therapy, Pope Air Force Base Dental Officers, June, 1992.                                                                                      | Pr |
| Shields W: Mock Boards, Fort Gordon, Georgia, June, 1992.                                                                                                                        | Pr |
| Scott A.C., Vire D.E.: An Evaluation of the Ability of a Dentin Plug to control Extrusion of Thermoplasticized Gutta-Percha. <i>J of Endodontics</i> , February, 1992, 18:52-57. | P  |
| Vire D.E., Mikaloff R.W.: Reference Block for Auxillary Cones, <i>J of Endodontics</i> , May, 1992, 18:249-250.                                                                  | P  |
| McDonald M.N., Vire D.E.: Chloroform in the Endodontic Operatory, <i>J of Endodontics</i> , June, 1992, 18:301-303.                                                              | P  |
| Scott A.C., Vire D.E.: An Evaluation of the Thermafil Endodontic Obturation Technique, <i>J of Endodontics</i> , July, 1992, 18:340-343.                                         | P  |
| DeWald E.J: Glassionomers, Self-Evaluation Test AGD, <i>Gen Dentistry J</i> , July, 1992.                                                                                        | P  |

#### DEPARTMENT OF FAMILY PRACTICE

- |                                                                                                                               |    |
|-------------------------------------------------------------------------------------------------------------------------------|----|
| FitzHarris J: 1st Armored Division DISCOM Surgeon. 7th Military Medicine Conference, Desert Shield/Storm, USUHS, April, 1992. | Pr |
|-------------------------------------------------------------------------------------------------------------------------------|----|

\* P = publication, Pr = presentation, Ab = abstract

### III. PUBLICATIONS, PRESENTATIONS, AND ABSTRACTS BY DEPARTMENT/SERVICE AND AUTHOR (cont)

\*TYPE

#### DEPARTMENT OF FAMILY PRACTICE (cont)

- |                                                                                                                                                                                                                                                                                                                                                |    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| Lux D: Falciparum Malaria in Pregnancy. Southern Medical Association Annual Scientific Assembly, Atlanta, Georgia, November, 1991.<br><b><u>Best Scientific Paper Award</u></b> in Physicians-In-Training Competition.                                                                                                                         | Pr |
| Clark J: Experience of the 82nd Airborne Division Surgeon in Operation Desert Shield/Desert Storm. 7th Annual Military Medicine Conference, Bethesda, MD, April, 1992.                                                                                                                                                                         | Pr |
| McGlaughlin V: Work and Pregnancy Outcome in Military and Non-Military Women. 13th Annual Faculty Development Fellows Symposium, University of North Carolina, Chapel Hill, June, 1992.                                                                                                                                                        | Pr |
| Carnahan W., McGlaughlin V: Hirschsprung's Disease in Dizygotic Twins. Southern Medical Association Annual Scientific Assembly, Atlanta, Georgia, November 1991.                                                                                                                                                                               | Pr |
| Schooff M: Influences in Medical Specialty Selection of the 1991 Graduates of the Uniformed Services University of the Health Sciences. XVIIth Annual Uniformed Services Academy of Family Physicians Scientific Assembly, Oakland, California, May, 1992.<br><b><u>First Place Award</u></b> in the Resident Clinical Investigation category. | Pr |
| Marsden J: Misdiagnosis of an infant with decreased movement of an extremity: a case report and review of the literature. XVIIth Annual Uniformed Services Academy of Family Physicians Scientific Assembly, Oakland, California, May, 1992.                                                                                                   | Pr |
| Hudson M: Trichotillomania and intestinal bezoar: a case report. XVIIth Annual Uniformed Services Academy of Family Physicians Scientific Assembly, Oakland, California, May, 1992.                                                                                                                                                            | Pr |
| Hawkins M: Henoch-Schonlein Purpura. XVIIth Annual Uniformed Services Academy of Family Physicians Scientific Assembly, Oakland, California, 1992.                                                                                                                                                                                             | Pr |
| McGlaughlin, V., Clark J.: Preparation for Operation Desert Storm: Experience in the Forward Support Medical Company. 7th Annual Military Medicine Conference, Bethesda, MD, April, 1992.                                                                                                                                                      | Ab |

\* P = publication, Pr = presentation, Ab = abstract

### III. PUBLICATIONS, PRESENTATIONS, AND ABSTRACTS BY DEPARTMENT/SERVICE AND AUTHOR (cont)

#### \*TYPE

#### DEPARTMENT OF MEDICINE

- Pearl L, Choi Y: Marijuana as a cause of Myocardial infarction. *Int J Cardio*, 1992;34:353. P
- Choi Y: Serum enzyme monitoring in asthma patients. *Pediatrics* (accepted for publication). P
- Ulrich M: Comparative study of readability levels between nurse generated and commercially prepared patient information materials. Phyllis J Vernonick Research Course, Walter Reed Army Medical Center, April, 1992. Pr
- Ulrich M: Cultural considerations in Pharmacotherapy. 13th Annual Physician Assistant Refresher Course, Fayetteville, NC, March, 1992. Pr
- Byrn B: Maternal Variables and Characteristics associated with vertical transmission of HIV-I. VIII International AIDS Conference, Amsterdam, July, 1992. Pr

#### PREVENTIVE MEDICINE ACTIVITY

- Lado L: Managing Mental Health needs for HIV infected health care workers. The Fourth International Conference on AIDS and Social Work, Washington, DC, July, 1992. Pr
- MaGruder C: Developing a Health Promotion Program for Individuals Infected with HIV. HIV Congress 1991, QLT/CONGREX, First International Conference, Amsterdam, September, 1991. Pr

#### DEPARTMENT OF RADIOLOGY

- Abreu S.H., Nostrand D., Zeissman H.A., eds.: *Selected Atlases of Bone Scintigraphy*, Springer-Verlag New York, Inc., New York, 1992. P
- Abreu S.H: Use and Abuse of Nuclear Medicine Studies to Maintain Fitness and Wellness. XVIth Annual Uniformed Services Academy of Family Practitioners Scientific Assembly and Academic Course, Oakland, California, May, 1992. Pr

\* P = publication, Pr = presentation, Ab = abstract

### III. PUBLICATIONS, PRESENTATIONS, AND ABSTRACTS BY DEPARTMENT/SERVICE AND AUTHOR (cont)

\*TYPE

#### DEPARTMENT OF RADIOLOGY

- McDevitt G., et al.: Diffuse Abdominal Uptake of Technetium-99m-Methylene Diphosphonate In a Patient on Continuous Ambulatory Peritoneal Dialysis During Bone Scintigraphy, *J Nuclear Medicine*, November, 1991, in print. P

#### SOCIAL WORK SERVICE

- Gill D: Family Assessments for Medical Students: Making Behavioral Science Fun. Society of Teachers of Family Medicine, Annual Meeting, St Petersburg, FL, January, 1992. Pr

#### DEPARTMENT OF SURGERY

- Vause N., Letterie G.: Muellerian Tract Abnormalities and Associated Auditory Defects. *J Reproductive Medicine*, November, 1991, 36:765-768. P
- Elledge E.S., Whiddon R.G., Fraker J.T., Stambaugh, K.I.: The Effect of Topical Oral Clindamycin Antibiotic Rinses on the Bacterial Content of Saliva on Healthy Human Subjects, *Otolaryngology, Head and Neck Surgery Journal*, December, 1991, 105;6:836-839. P
- Behrens J., Stannard J., Bucknell A.: The Incidence of HIV Seropositivity in Severe Trauma, *J of Bone and Joint Surgery*, June, 1992, 74A:5. P
- Brown J: Evaluating the Effectiveness of the Upper Extremity, Musculoskeletal Evaluation and Treatment Course to Practice. Army Medical Specialist Corps, Mary L. Hamrick Research Course, Silver Spring, MD, August, 1992. Pr
- Stannard J: Pressure Absorption During Parachute Landing Falls. Lower Extremity Assistance for Parachutist (LEAP) Task Force Meeting, Washington, DC, October, 1991. Pr
- Stannard J: Femur Fractures in Infants - A New Therapeutic Approach. Society of Military Orthopaedic Surgeons, El Paso, TX, November, 1991. Pr
- Stannard J: Pressure Absorption During Parachute Landing Falls. Society of Military Orthopaedic Surgeons, El Paso, TX, November, 1991. Pr
- Founders Award for Best Military Research Winner.**

\* P = publication, Pr = presentation, Ab = abstract

### III. PUBLICATIONS, PRESENTATIONS, AND ABSTRACTS BY DEPARTMENT/SERVICE AND AUTHOR (cont)

#### \*TYPE

#### DEPARTMENT OF SURGERY (cont)

- Stannard J: Femur Fractures in Infants - A New Therapeutic Approach. Pr  
59th Annual Meeting of the American Academy of Orthopaedic Surgeons,  
Washington, DC, February, 1992.
- Stannard J: Intermittent Compression of the Plantar Venous Plexus Following  
Total Joint Arthroplasty. Ninth Combined Meeting of the Orthopaedic  
Associations of the English Speaking World, Toronto, Canada, June, 1992. Pr
- Vause N: Lessons Learned During Operation Desert Storm and Marketing Military  
Audiology. Military Audiology Short Course, Nashville, TN, April, 1992. Pr
- Vause N: Milestones for Military Audiology during ODS. Colorado  
Otolaryngology and Audiology Conference, Breckenridge, CO, March, 1992. Pr

#### DEPARTMENT OF SURGERY (Urology Service)

- Quinones D., Crawford E.D: Seminal Vesiculectomy, *Masters of Surgery - Urology*  
1992 Edition. P
- Quinones D: Testicular Tumors - Diagnosis and Treatment. Pr  
Annual PA Conference, Fayetteville, NC, April, 1992.
- Quinones D: Prostatitis - Diagnosis and Treatment. Pr  
Annual PA Conference, Fayetteville, NC, April, 1992.
- Freyfogle E.B: What's New In Urology. Annual PA Conference, Pr  
Fayetteville, NC, April, 1992.
- Freyfogle E.B: Vaso-vasostomy - A Military Dilemma. Pr  
Kimbrough Urology Annual Conference, November, 1991.
- Freyfogle E.B: Forward Surgical Team - Amerikanisches Einsatz Konzept. Pr  
Deutsche Gesellschaft fuer Wehrmedizin und Wehrpharmazie, October, 1992.

#### VETERINARY SERVICES

- Dutton R: Utilization and Health Problems in the Military Pr  
Working Dog. North American Veterinary Conference,  
Orlando, FL, January, 1992.

\* P = publication, Pr = presentation, Ab = abstract



**REPORT DATE:** 09/15/92

**PROTOCOL #:** 92001

## **DETAIL SUMMARY SHEET**

**TITLE:** The Nedocromil Sodium Inhalation Aerosol Clinical Experience Study:  
An Evaluation of Nedocromil Sodium Inhalation Aerosol in  
Symptomatic Patients with Mild to Moderate Asthma

**KEYWORDS:** asthma, asthma treatment

**PRINCIPAL INVESTIGATOR:** McGlaughlin, Victor MAJ MC

**DEPARTMENT:** Department of Family Medicine

**STATUS:** Terminated

**APPROVAL DATE:** Oct 1991

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

### **STUDY OBJECTIVE:**

To demonstrate improvements in symptoms and global indices of lifestyle in symptomatic patients with mild-moderate asthma after four weeks of treatment with Nedocromil Sodium.

### **TECHNICAL APPROACH:**

Multicenter, open label trial. Weekly symptom assessment, pulmonary function testing, and lifestyle indices assessment.

### **PRIOR AND CURRENT PROGRESS:**

Womack Army Medical Center was not selected as an investigation site, and no patients were enrolled. Protocol closed 30 September 1992.

### **CONCLUSIONS:**

None.

**REPORT DATE:** 05/22/92

**PROTOCOL #:** 92002

## **DETAIL SUMMARY SHEET**

**TITLE:** Long-Acting Converting Enzyme Inhibition Use in Elderly, Hypertensive Patients:  
A Nationwide Study.

**KEYWORDS:** hypertension, elderly, enzyme inhibition use

**PRINCIPAL INVESTIGATOR:** Swackhammer, Randy MAJ MC

**DEPARTMENT:** Department of Medicine  
Internal Medicine

**STATUS:** Completed  
**APPROVAL DATE:** Oct 1991

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

### **STUDY OBJECTIVE:**

This trial proposed to examine a national database of elderly, hypertensive patients managed with long-acting converting enzyme inhibitors to assess clinical usage and effects.

### **TECHNICAL APPROACH:**

This study was a retrospective, multi-center drug use evaluation of the clinical usage and effects in the elderly (age over 60 years) of ACE inhibitors. Outpatient charts of identified patients were reviewed and case forms completed. Patient, Medication, Safety, and Clinical Response Data was collected.

### **PRIOR AND CURRENT PROGRESS:**

This study was completed in May 92 with a total of thirty subjects entered into the study.

### **CONCLUSIONS:**

Many of the patients are not controlled despite Combination Therapy. I suspect compliance may be a factor.

**REPORT DATE:** 07/30/92

**PROTOCOL #:** 92003

## **DETAIL SUMMARY SHEET**

**TITLE:** A comparison of the efficacy, safety, and tolerance of Cefibuten 300mg given BID and Augmentin 500mg given TID in the Treatment of Community Acquired Pneumonia.

**KEYWORDS:** Pneumonia, Augmentin, Cefibuten

**PRINCIPAL INVESTIGATOR:** Weightman, George LTC MC

**DEPARTMENT:** Department of Family Medicine

**STATUS:** Ongoing

**APPROVAL DATE:** Jan 1992

**EST COMPLETION DATE:** Jun 1993

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

### **STUDY OBJECTIVE:**

To compare the efficacy, safety, and tolerance of high dose Cefibuten (300mg BID) with that of Augmentin (500mg TID) in the treatment of pneumonia in thirty adults.

### **TECHNICAL APPROACH:**

A randomized, single blind comparison drug study. Data is collected via subjective and objective assessment by the physician in the pre-treatment, during treatment and post treatment phase. Data is reported by standardized forms. Statistical analysis will be provided by the sponsor.

### **PRIOR AND CURRENT PROGRESS:**

Progress of the clinical trial includes: organization of the research team, solicitation of evaluable subjects, community awareness and practical experience with the technical aspects of protocol administration.

To date, eleven potential patients have been screened for enrollment with a subsequent participation of five. There have been no serious adverse events noted.

Manpower consists of: the principal investigator, the associate investigator and a full time study coordinator provided by the sponsor. The Womack Army Medical Center Department(s) of Pathology, Radiology and Pharmacy provide technical support.

### **CONCLUSIONS:**

At present, availability of qualified patients has been limited. It is anticipated that this situation will improve with the onset of the traditional cold and flu season.

**REPORT DATE:** 08/17/92

**PROTOCOL #:** 92004

### **DETAIL SUMMARY SHEET**

**TITLE:** A comparison of the efficacy, safety, and tolerance of Ceftibuten 400mg in the fed and fasted state and Augmentin Amoxicillin/Clavulante 1.5gm in the fed state in the Treatment of Acute Exacerbations of Chronic Bronchitis.

**KEYWORDS:** Bronchitis, Augmentin, Ceftibuten

**PRINCIPAL INVESTIGATOR:** Greenberg, Bruce, MAJ MC

**DEPARTMENT:** Department of Family Medicine

**STATUS:** Ongoing

**APPROVAL DATE:** Jan 1992

**EST COMPLETION DATE:** Jun 1993

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

#### **STUDY OBJECTIVE:**

To compare the efficacy, safety, and primarily, the GI tolerance of once daily Ceftibuten in both the fed and fasted state with that of Augmentin given TID in the fed state in the treatment of acute exacerbations of chronic bronchitis.

#### **TECHNICAL APPROACH:**

A randomized, single blind comparison drug study. Data is collected via subjective and objective assessment by the physician in the pre-treatment, during treatment and post treatment phase. Data is reported by standardized forms. Statistical analysis will be provided by the sponsor.

#### **PRIOR AND CURRENT PROGRESS:**

Progress of the clinical trial includes: organization of the research team, solicitation of evaluable subjects, community awareness and practical experience with the technical aspects of protocol administration.

To date, eighteen potential patients have been screened for enrollment with a subsequent participation of four. There have been no serious adverse events noted.

Manpower consists of: the principal investigator, the associate investigator and a full time study coordinator provided by the sponsor. The Womack Army Medical Center Department(s) of Pathology, Radiology and Pharmacy provide support.

#### **CONCLUSIONS:**

At present, availability of qualified patients has been limited. It is anticipated that this situation will improve with the onset of the traditional cold and flu season.

**REPORT DATE:** 10/09/92

**PROTOCOL #:** 92005

### **DETAIL SUMMARY SHEET**

**TITLE:** The influence of work on the outcome of pregnancy in military and non-military nulliparous women

**KEYWORDS:** Pregnancy outcome, work, pregnancy complications

**PRINCIPAL INVESTIGATOR:** McGlaughlin, Victor MAJ MC

**DEPARTMENT:** Department of Family Medicine

**STATUS:** Ongoing

**APPROVAL DATE:** Jan 1992

**EST COMPLETION DATE:** May 1993

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

#### **STUDY OBJECTIVE:**

To determine: 1) if pregnant soldiers have different work and experiences than pregnant civilian workers, 2) if soldiers have a higher rate of complicated pregnancy than civilian workers.

#### **TECHNICAL APPROACH:**

This is a prospective cohort study. Each woman consenting to participate completed a questionnaire at 28 weeks gestation, seeking information about work activity and exposures, sources of stress and support at home and in the work place, wellness behaviors and demographics. The responses of pregnant soldiers and pregnant women who reported working outside the home were compared.

#### **PRIOR AND CURRENT PROGRESS:**

For this preliminary report, the responses of 25 soldiers and 13 civilian workers were reviewed. Soldiers reported more hours worked per week during pregnancy, and were more likely to have a lower total household income, to be single and to be black. No significant differences in work activity or exposure were evident from this small sample.

Previous retrospective studies indicated a greatly increased risk of pregnancy complications for soldiers over their civilian counterparts. However, no comparison of the actual work performed was made between the groups. While soldiers and civilian workers are similar in several important work dimensions, they are very different in hours worked per week, and may also be demographically different. Data for specific complications of pregnancy are pending but, together with this antepartum information, may help to better define the risks for the pregnant soldier.

#### **CONCLUSIONS:**

None. Data still being collected.

**REPORT DATE:** 11/23/92

**PROTOCOL #:** 92006

## **DETAIL SUMMARY SHEET**

**TITLE:** Tick-Borne Disease Surveillance in Febrile, Hospitalized Patients

**KEYWORDS:** tick-borne disease, Lyme disease, Rocky Mountain Spotted Fever

**PRINCIPAL INVESTIGATOR:** McGlaughlin, Victor MAJ MC

**DEPARTMENT:** Department of Family Medicine

**STATUS:** Ongoing

**APPROVAL DATE:** Feb 1992

**EST COMPLETION DATE:** Jan 1993

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

### **STUDY OBJECTIVE:**

A prospective study to determine the relative frequencies of several common tick-borne diseases such as Lyme disease, Ehrlichiosis, Q fever, and Rocky Mountain Spotted Fever in the patients admitted to Womack Army Medical Center.

### **TECHNICAL APPROACH:**

The study population consists of all consenting patients, 18 years and older, admitted to Womack. Patients will be enrolled if they have a history of tick exposure within the preceding two weeks. PCR, CBC and liver function tests will be performed. A convalescent titer will be determined from all participating patients 21-28 days after the acute titer is drawn.

### **PRIOR AND CURRENT PROGRESS:**

A total of 22 patients have been included into the inpatient study to this date. LFT's and CBC's have been followed every 3 days while in-house. Acute titers have been obtained at that time as well. Convalescent titers have been extremely difficult to obtain and when obtained are often later than four weeks.

### **CONCLUSIONS:**

None. Data still being collected.

**REPORT DATE:** 10/12/92

**PROTOCOL #:** 92007

**DETAIL SUMMARY SHEET**

**TITLE:** Fluoride Concentrations in Human Bone

**KEYWORDS:** fluoride, bone fluoride concentrations

**PRINCIPAL INVESTIGATOR:** Davis, Randy MAJ DC

**DEPARTMENT:** Dental Activity WAMC

**STATUS:** Completed

**APPROVAL DATE:** Mar 1992

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

**STUDY OBJECTIVE:**

To obtain data on bone fluoride concentrations in the present population using subjects with a known history of systemic fluoride exposure.

**TECHNICAL APPROACH:**

Bone samples were obtained through cooperation of the Operating Room staff and Orthopedic Surgery. Surgical procedures were identified in which it was anticipated that bone would be removed from patients and discarded. No additional bone was removed for this study. Prior to surgery, the patients were interviewed, a summary of medical history recorded and the best possible fluoride exposure history obtained.

**PRIOR AND CURRENT PROGRESS:**

12 samples were collected, and all had normal fluoride concentrations. The principal investigator was unable, however, to correlate these bone levels with the water supply fluoride level at the subject's home of record (no response from the various utility departments). An ongoing effort to secure this data is being made.

**CONCLUSIONS:**

None.

**REPORT DATE:** 10/01/92

**PROTOCOL #:** 92008

### **DETAIL SUMMARY SHEET**

**TITLE:** Fort Bragg Tick-Borne Disease Study: Womack Family Practice Clinic  
(Non-Active Duty Outpatients)

**KEYWORDS:** Tick-borne disease, Ehrlichiosis, Lyme disease

**PRINCIPAL INVESTIGATOR:** Goforth, Gary LTC MC

**DEPARTMENT:** Department of Family Medicine

**STATUS:** Ongoing

**APPROVAL DATE:** Mar 1992

**EST COMPLETION DATE:** Dec 1993

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

#### **STUDY OBJECTIVE:**

To determine the relative frequency of several common tick-borne diseases such as Lyme disease, ehrlichiosis, Q fever, and Rocky Mountain Spotted Fever (RMSF) in a non-active duty military population.

#### **TECHNICAL APPROACH:**

This is a prospective study utilizing serological and questionnaire data. Manpower consists of 1) the Principal and Associate Investigators, 2) WAMC laboratory personnel and 1 shipping technician, and 3) Family Practice Clinic Nurse(s) - 2 LPN's.

#### **PRIOR AND CURRENT PROGRESS:**

To date, there have been 25 subjects enrolled from 10 March 92 - 30 September 92. There have been no serious adverse events noted.

All acute serologic specimens have been collected for the study. Five convalescent specimens and questionnaires have been received and forwarded to the CDC. The study investigators have completed multiple follow-up attempts to acquire the remainder of the convalescent sera and questionnaires including phone calls (3) and letters to the study subjects. Final results are based on both acute and convalescent sera results.

#### **CONCLUSIONS:**

None. Data still being collected.



**REPORT DATE:** 12/01/92

**PROTOCOL #:** 92009

### **DETAIL SUMMARY SHEET**

**TITLE:** A comparison of functional recovery rates using circumferential, collateral and focal continuous compression following grade II ankle inversion injuries

**KEYWORDS:** ankle sprain, compression, functional tests

**PRINCIPAL INVESTIGATOR:** O'Keefe, Ellen CPT SP

**DEPARTMENT:** Department of Surgery  
Physical Therapy  
Orthopedics

**STATUS:** Ongoing  
**APPROVAL DATE:** Mar 1992  
**EST COMPLETION DATE:** Jun 1993

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

#### **STUDY OBJECTIVE:**

To compare the rates of functional recovery using different modes of continuous compression following grade II ankle inversion injuries in a healthy male active duty military population.

#### **TECHNICAL APPROACH:**

This study will examine 300 male active duty personnel with a diagnosis of acute grade II ankle inversion injury by clinical exam. After informed consent, the patient will be randomly assigned to one of three continuous compression groups: circumferential, collateral or focal. Each of the patients will receive standard physical therapy treatment on an out-patient basis. The rate of functional recovery will be measured through the use of an eleven level post-sprain function scale. Clinical measurements will also be used to assess progress in the areas of range of motion, swelling, subjective pain, strength and proprioception.

#### **PRIOR AND CURRENT PROGRESS:**

To date, 65 patients have been screened for enrollment with a subsequent participation of 38. There have been no serious adverse events noted.

Manpower consists of the principal investigator, the associate investigator, a physical therapy technician and an orthopedic technician. WAMC Department of Radiology provides technical support.

#### **CONCLUSIONS:**

At present, there is difficulty recruiting subjects for this study, although qualified patients are available. Several actions have been taken to address this and it is anticipated that this situation will improve.

**REPORT DATE:** 09/22/92

**PROTOCOL #:** 92010

### **DETAIL SUMMARY SHEET**

**TITLE:** Ultrasound guided percutaneous needle core biopsy

**KEYWORDS:** breast mass, breast cancer, breast biopsy

**PRINCIPAL INVESTIGATOR:** Burke, Brian CPT MC

**DEPARTMENT:** Department of Radiology

**STATUS:** Ongoing

**APPROVAL DATE:** Mar 1992

**EST COMPLETION DATE:** May 1993

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

#### **STUDY OBJECTIVE:**

This study seeks to evaluate radiologic aspects of core biopsy and to discern if the method can effectively diagnose breast carcinoma pre-operatively.

#### **TECHNICAL APPROACH:**

Prospective, blinded study of fifty (50) patients who would undergo ultrasound-guided needle core breast biopsy, followed by surgical excisional biopsy, and have independent pathologic correlation of their biopsy results. Subjects are those women with suspicious lesions who would undergo surgical biopsy anyway.

#### **PRIOR AND CURRENT PROGRESS:**

No study subjects enrolled to date, because there have been no referrals from clinicians.

#### **CONCLUSIONS:**

None.

**REPORT DATE:** 07/19/92

**PROTOCOL #:** 92011

### **DETAIL SUMMARY SHEET**

**TITLE:** A double-blind, placebo controlled, parallel group, multicenter study of the use of weekly Azithromycin against the development of Mycobacterium Avium Complex Disease in HIV infected people

**KEYWORDS:** HIV, Mycobacterium Avium Complex, Azithromycin

**PRINCIPAL INVESTIGATOR:** Williams, Richard MAJ MC

**DEPARTMENT:** Department of Medicine  
Preventive Medicine  
Internal Medicine

**STATUS:** Ongoing  
**APPROVAL DATE:** May 1992  
**EST COMPLETION DATE:** Jul 1994

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

#### **STUDY OBJECTIVE:**

To study the efficacy of azithromycin in prophylaxis of MAC infection in patients with HIV infection and low CD4 counts.

#### **TECHNICAL APPROACH:**

This study will enroll all patients with CD4 counts <100/ul who have negative MAC cultures. Screening and baseline evaluations will include a full medical history and physical exam. Blood tests, stool culture, CXR, and baseline audiometry will be performed. Patients will then be randomized in double-blind fashion to receive azithromycin 1200mg or placebo as a single dose once a week. Patients will be evaluated clinically once a month and at three months labs and MAC culture will be obtained.

#### **PRIOR AND CURRENT PROGRESS:**

To date, one study subject has been enrolled. There have been no serious adverse events noted.

#### **CONCLUSIONS:**

None.

**REPORT DATE:** 08/09/92

**PROTOCOL #:** 92012

### **DETAIL SUMMARY SHEET**

**TITLE:** The Prevalence of Degenerative Joint Disease of the Spine in Airborne Infantry, Non-Airborne Infantry, and Non-Airborne Combat Service Support Personnel

**KEYWORDS:** degenerative joint disease, spine, chronic back injury

**PRINCIPAL INVESTIGATOR:** Craig, Stephen MAJ MC

**DEPARTMENT:** Preventive Medicine Service  
WRAIR

**STATUS:** Completed  
**APPROVAL DATE:** Feb 1992

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

#### **STUDY OBJECTIVE:**

To determine the prevalence of chronic back injury and degenerative joint disease in the study populations.

#### **TECHNICAL APPROACH:**

This cross-sectional study was conducted in two parts: Part I consisted of a questionnaire and medical records review and Part II consisted of 3 lateral radiographs of the spine. All investigative personnel were from WRAIR and WRAMC. Radiology assets from Womack Army Medical Center, Fort Bragg, NC and BACH, Fort Campbell, KY were utilized. Troops from the 82nd, 101st, and 18th COSCOM comprised the study population.

The project was completely funded by WRAIR.

There were a total of two hundred forty five (245) subjects enrolled. There were no adverse reactions noted.

#### **PRIOR AND CURRENT PROGRESS:**

Part I was completed, analyzed, and formally presented at the end of year Residency Advisory Committee Meeting on WRAIR on 26 June 92. Part II was completed by mid-July and is currently being analyzed.

#### **CONCLUSIONS:**

1) Blacks are less likely to have chronic back pain than whites whether they jump or not. 2) Only night jumping increased the likelihood that a troop would have chronic back pain. 3) Marching or running with a ruck did not increase the odds that a soldier would have chronic back pain.

**REPORT DATE:** 10/28/92

**PROTOCOL #:** 92013

## **DETAIL SUMMARY SHEET**

**TITLE:** Immunization of Military Personnel with Hepatitis A Vaccine

**KEYWORDS:** Hepatitis A, immunization

**PRINCIPAL INVESTIGATOR:** Sjogren, Maria H LTC MC

**DEPARTMENT:** USAMRIID Medicine  
WRAIR

**STATUS:** Ongoing  
**APPROVAL DATE:** 1994

**FUNDING:** Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

### **STUDY OBJECTIVE:**

1) To make the hepatitis A vaccine available to DOD beneficiaries who may be at risk of contracting hepatitis A as a result of training in or deployment to areas where hepatitis A is endemic and 2) to establish the immunogenicity and reactogenicity of this vaccine when it is given as a double dose compared with two single doses administered one month apart.

### **TECHNICAL APPROACH:**

The vaccine will be made available in single-blind fashion to members of the Joint Special Operations Command, according to one of two regiments: approximately half of the individuals will receive a double vaccine dose on day 0, and a saline placebo on day 30; the remainder will receive a single vaccine dose in one arm and saline placebo in the other on day 0, and a single vaccine dose on day 30. Both groups will be boosted at one year with vaccine to anchor the antibody response. Blood samples for serologic analysis will be obtained prior to the first dose (day 0), prior to the booster dose (1 year), and at the conclusion of the project (2 years).

No use of WAMC facilities is anticipated. All clinical work will be conducted within the confines of the JSOC.

### **PRIOR AND CURRENT PROGRESS:**

This hepatitis A vaccine at present is an investigational new drug in the U.S. A New Drug Application is in the process of being submitted by the manufacturer to the FDA for this vaccine. This submission is based upon results of studies in many thousands of human volunteers. A recent, relatively small, study performed at Fort Campbell indicated that there was no significant difference in either the seroconversion rate or the geometric mean antibody titer among individuals vaccinated with a double dose on day 0 and those vaccinated with a single dose on days 0 and 30. This study has only recently begun; therefore, no progress report is available at this time.

### **CONCLUSIONS:**

None.

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